



NDA 15-034/S-034

Parke-Davis
Attention: James A. Parker, Jr.
Director, Advertising and Labeling
Worldwide Regulatory Affairs
201 Tabor Road
Morris Plains, NJ 07950

Dear Mr. Parker:

Please refer to your supplemental new drug application dated August 14, 1998, received August 17, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ponstel (mefenamic acid) Capsules, 250 mg.

We acknowledge receipt of your submission dated August 14, 1998.

This supplemental new drug application provides for additions to the package insert to add a Geriatric Use subsection in accordance with 21 CFR 201.57(f)(10).

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted August 14, 1998).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 15-034/S-034." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Carmen DeBellas, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Jonca Bull, M.D.
Acting Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic
Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Jonca Bull

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